



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,400	09/12/2003	J. Christopher Marmo	D-4108	6665
33197	7590	02/03/2006	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP			PREBILIC, PAUL B	
4 VENTURE, SUITE 300				
IRVINE, CA 92618			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,400

Applicant(s)

MARMO ET AL.

Examiner

Paul B. Prebilit

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-108, 112, 113, 118, 121-130, 132, 134-137, 139-141, 150 and 160-177 is/are pending in the application.
- 4a) Of the above claim(s) 55-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-102, 105-108, 112, 113, 118, 121-126, 132, 134-137, 139-141, 150, 160-166 and 171-177 is/are rejected.
- 7) ☒ Claim(s) 103, 104, 127-130 and 167-170 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election with traverse of Group III in the reply filed on November 16, 2005 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the examiner to search the other two inventions. This is not found persuasive because there would clearly be additional searching required to examine all three inventions because it would require searching at least the method of making the device classes and subclasses (Group II), but also a more detailed search of the corneal appliance that could be read on a contact lens or an intraocular lens (Group I).

The requirement is still deemed proper and is therefore made FINAL.

Claims 55-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 16, 2005.

The Examiner would like to clarify any confusion created by a typographical error made in the Office action mailed October 17, 2005. In particular, Group III should have included claims 134-137 and not claim 143. Claim 143 was cancelled prior to that Office action.

Specification

The abstract of the disclosure is objected to because it is not directed to the presently claimed invention. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive of the presently elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 84 is objected to because of the following informalities: On line 5 of claim 84, "the lens body" lacks antecedent basis. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 81-83, 86, 87, 89, 90, 96, and 108 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 8-11, 13, and 16 of copending Application No. 11/183,191 in view of *Silvestrini et al* (US 5,300,118). The present claims are read on by the copending

claims except that the present claims do not disclose the formation of a pocket, as the copending claims require. However, Silvestrini teaches that it was known to form a pocket for the ocular device in similar procedures; see Figure 15b and column 11, lines 13-34. Therefore, it is the Examiner's position that it would have been obvious to form a pocket in the procedure of the present claims in order to make insertion of the ocular device easier.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 81-84, 87-95, 97, 105, 106, 108, and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Peyman (US 5,964,748). Peyman anticipates the claim language where "substantially" is considered to be a broad term (see MPEP 2173.05(b) that is incorporated herein by reference); see Figure 19-27 and 32-40, column 12, line 26 to column 13, line 14 and column 14, lines 39 et seq. The vision correction device as claimed is made of the ocular material of Peyman (428,430), and the incision as claimed is the incision (418) of Peyman.

Upon review of the provisional applications relied upon for domestic priority, the Examiner determined that the present claims have an effective filing date of September 12, 2003.

With regard to claim 84, Applicants are directed to Figures 46-53 and column 18, line 15 et seq.

With regard to claim 118, Applicants are directed to column 25, lines 1-10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 96, 100-102, and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748) in view of Brown et al (US 4,959,353). Peyman meets the claim language fully except for the application of a healing agent as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been obvious to apply a healing agent to the cornea in the Peyman method in order to promote healing therein.

With regard to claim 100, Applicants are directed to column 4, lines 43-57 of Brown.

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748) in view of Perez (US 6,880,558). Peyman meets the claim language except for the use of a vacuum to lift up a corneal flap or corneal tissue. However, Perez teaches that it was known to do the same in similar procedures; see Figure 5 and column 10, lines 35-58. Therefore, it is the Examiner's position that it would have been

Art Unit: 3738

obvious to lift the flap or tissue in the Peyman procedure with a vacuum as taught by Perez for the same reasons that Perez does the same and in order to reduce trauma to the corneal tissue as compared to other tissue moving procedures in the art.

Claims 99, 121-123, 126, 132, 139, 140, 141, 160, 163, 165, 166, 172, 173, 175, and 176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748) in view of Miller (US 6,335,006). Peyman meets the claim language except for the use of a liquid to loosen the epithelial layer as claimed. However, Miller teaches that it was known to use liquids of various types to loosen epithelial layers; see column 1, line 65 to column 3, line 29. Therefore, it is the Examiner's position that it would have been obvious to use the Miller procedure to loosen the epithelial tissue in Peyman's process for the same reasons that Miller does the same and in order to promote a clean separation of the tissue layers.

Claims 112, 113, 124, 125, 134-137, 161, and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman and Miller as applied to claims 99, 121-123, 126, 132, 139-141, 160, 163, 165, 166, 172, 173, 175, and 176 above, and further in view of Perez (US 2003/0220653). Peyman as modified by Miller fails to teach the use of a hypertonic solution to loosen the epithelial layer. However, Perez teaches that such solutions were known to the art at the time the invention was made; see paragraph [0150]. Therefore, it is the Examiner's position that it would have been obvious to utilize a hypertonic solution for the loosening procedure of Miller for the same reasons that Perez utilizes the same and in order to prevent the use of toxic residues to the eye tissue that could cause toxicity problems after surgery.

With regard to claims 134-137, Applicants are directed to see paragraphs [0094] to [0105] of Perez.

Claim 164 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman and Miller as applied to claims 99, 121-123, 126, 132, 139-141, 160, 163, 165, 166, 172, 173, 175, and 176 above, and further in view of Perez (US 6,880,558). Peyman as modified by Miller fails to disclose the use of a vacuum lift corneal tissue during corneal procedures. However, However, Perez teaches that it was known to do the same in similar procedures; see Figure 5 and column 10, lines 35-58. Therefore, it is the Examiner's position that it would have been obvious to lift the flap or tissue in the Peyman procedure with a vacuum as taught by Perez for the same reasons that Perez does the same and in order to reduce trauma to the corneal tissue as compared to other tissue moving procedures in the art.

Claims 171 and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman and Miller as applied to claims 99, 121-123, 126, 132, 139-141, 160, 163, 165, 166, 172, 173, 175, and 176 above, and further in view of Peyman (US 2004/0015234). Peyman ('748) discloses utilizing various instruments to make incisions in the cornea, but fails to teach that use of a microkeratome. However, Peyman ('234) teaches that it was known to utilize a microkeratome to make incisions in similar corneal procedures in the art. Therefore, it is the Examiner's position that it would have been obvious to utilize a microkeratome to make the incisions of Peyman ('748) for the same reasons that Peyman ('234) utilizes the same and in order to make a very clean and precise incision as compared to other procedures of the art.

Claim 177 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman and Miller as applied to claims 99, 121-123, 126, 132, 139-141, 160, 163, 165, 166, 172, 173, 175, and 176 above, and further in view of Brown (US 4,959,353). Peyman as modified by Miller fails to disclose the application of a healing agent as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been obvious to apply a healing agent to the cornea in the Peyman method in order to promote healing therein.

Allowable Subject Matter

Claims 103, 104, 127-130, and 167-170 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone

Art Unit: 3738

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilit", with a stylized, cursive script.

Paul Prebilit
Primary Examiner
Art Unit 3738